STATEMENT

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PhRMA's Position on Safe Disposal of Unused Medicines
For the King County Board of Health
February 21, 2013

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments to the King County Board of Health regarding the Drug Enforcement Administration's (DEA) proposed rulemaking to implement the Secure and Responsible Disposal Act of 2010. While PhRMA will submit official comments to the agency, PhRMA appreciates the additional opportunity to outline the industry's position on safe disposal of unused medicines.

PhRMA is a voluntary, nonprofit association that represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures and treatments. Since 2000, PhRMA member companies have invested over $500 billion in the search for new treatments and cures, including an estimated $49.5 billion in 2011 alone.

Because there are multiple sources of unused medicines, there must be a continued focus on all sources of diversion.

PhRMA shares King County's concern regarding the growing non-medical use of prescription drugs. People who abuse prescription drugs get them from multiple sources and unused medicines actually constitute a very small portion of those sources. According to a 2011 Government Accountability Office (GAO) report,[1] controlled substances can be diverted in a variety of ways ranging from illegal or improper prescribing, prescription forgery, pharmacy thefts, or "doctor shopping" and can occur through illegal sales of controlled substances through internet pharmacies or pain clinics. [2] In the same report, GAO cites a recent proliferation of pain clinics in states such as Florida and Texas. Because of the multiple sources of medicines that are abused, it's important to include all of the participants in the drug manufacturing and distribution system in any effort to lessen abuse. PhRMA believes that it is important for both the Drug Enforcement Agency (DEA) and other law enforcement authorities to continue to focus on all of the critical sources of diverted medicines.

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[1] GAO. Prescription Drug Control: DEA Has Enhanced Efforts to Combat Diversion, but Could Better Assess and Report Program Results. Aug. 2011 (GAO-11-744).

[2] "According to the DEA, from fiscal years 2006 through 2009, rogue Internet pharmacies were a major source of this problem." "Prescription Drug Diversion: Combatting the Scourge." Statement for the record of Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA, before the Subcommittee on Commerce, Manufacturing and Trade Committee on Energy and Commerce, U.S. House of Representatives. March 1, 2012, page 2.

In-home disposal of unused medicines is the most efficient and environmentally friendly method.

PhRMA views "in-home" disposal of unused prescription medicines via the household trash as the most efficient and environmentally friendly method for disposal of unused post-consumer medicines. This approach includes simple, easy to follow steps, which is likely to contribute to consumers actually throwing out unused medicines. It does not require consumers to retain unused pharmaceuticals until a scheduled take back day, look up that location and make a special trip, or to otherwise modify one's regular routine to transport unused pharmaceuticals to a collection location. Because household trash is generally picked up at least once a week, this approach would be incorporated into consumer's regular routine, contributing to increased compliance rates. Furthermore, the costs of implementation are nominal compared to other disposal approaches.

"In-home" disposal effectively manages potential environmental issues by ensuring that the medicines will either be incinerated or disposed of in landfills which will effectively isolate waste from the physical environment. In-home disposal also avoids the re-concentration of pharmaceutical products inherent in any take-back program that poses a very real risk of theft, diversion and improper use. A major concern with take back programs is the environmental impact and cost of trips to a collection site or shipping the collected pharmaceuticals for destruction separately.

For products with specific FDA-approved disposal instructions, consumers should follow instructions.

For some medicines, the FDA or DEA may require product specific disposal options. For example, the DEA has specific policies regarding the disposal of controlled substances and the FDA may require specific disposal/return policies on prescription medicines that are subject to Risk Evaluation and Mitigation Strategies ("REMS"). Where these agencies recommend or require other disposal alternatives, PhRMA strongly encourages consumers to follow those instructions.

Community Take Back Programs must be operated and managed locally.

PhRMA does not oppose voluntary "take-back" programs and acknowledges that many local governments support this disposal alternative. Consequently, we believe that providing local authorities who choose to operate voluntary drug take-back programs with a legal mechanism that will permit their take back programs can be conducted consistent with federal law and regulations governing controlled substances is useful and helpful.

Governments should design, manage, and operate all aspects of the take-back programs, including conducting cost-benefit analyses and an impact evaluation to fully assess the degree to

which the program meets its stated objectives. Any program must be designed to meet all of the requirements of both state and federal law, including laws governing the handling of controlled substances, environmental protection laws, and laws governing worker safety. As mentioned previously, the DEA is currently receiving comments on a proposed rule that would govern community take back programs that collect controlled substances. Until those rules are finalized, any community take back program must have the active involvement of law enforcement officers.

Any program should confirm the available disposal options and the methods for shipping collected materials to the disposal location, consistent with the Department of Transportation (DOT) regulations for shipping waste in the category that state law defines for collected unused medicines and other consumer products.

Take-back programs should not shift program costs to others who are not directly served.

PhRMA opposes take-back programs that are designed to or have the effect of shifting program costs to individuals or communities not directly served by the program. The cost of any "take-back" program should be borne by the consumers served by that program. There are a variety of local funding options that the Board of Health might consider.

Any program that imposes legal responsibility and costs to operate on pharmaceutical companies because they are involved in interstate commerce, in our view, violates the "Dormant Commerce Clause" of the U.S. Constitution. In its simplest form, the Dormant Commerce Clause holds that a state (or municipal subdivision thereof) may not discriminate against interstate commerce in the imposition of fees, taxes, and other burdens in connection with the sale of products or services within its jurisdiction. In PhRMA's view, a program that violates the Dormant Commerce Clause is vulnerable to a legal challenge.

PhRMA urges the Board of Health to consider the efficiencies of administering a program as part of the local waste management system, funded by the resources provided by the people who are eligible to use the program.

Thank you for the opportunity to comment on the topic of disposal of unused medicines.